Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807 92

1 Company making the submission

JAN 2 6 2009

Name	Gish Biomedical, Inc
Address	22942 Arroyo Vista Rancho Santa Margarita, CA 92688-2600
Telephone	949-635-6200 voice 949-635-6291 fax martins@gishbiomedical com
Contact	Martin Sellers Director of Regulatory Affairs

2 Device

Proprietary Name	Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger with HA Coating
Common Name	Cardioplegia Heat Exchanger
Classification Name	Cardiopulmonary Bypass Heat Exchanger

3. Predicate Devices

Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger, K020106 and Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger with GBS™ Coating, K020106 Both manufactured by Gish Biomedical, Inc

4 Classifications Names & Citations

21 CFR 870 4240, Cardiovascular bypass heat exchanger, Class II, DTR, Cardiovascular

5 Description

The Gish Vision Blood Cardioplegia System with hyaluronan based coating (HA coating) consists of an extracorporeal heat exchanger and fluid administration set The heat exchanger consists of a one piece, stainless steel bellows, configured heat exchanger as the primary element to effect heat exchange This element is encased by a polycarbonate housing, which directs the blood through the outside convolutions of the stainless steel bellows, and therefore effects heat exchange while minimizing priming volume All materials of the heat exchanger are biocompatible

The device allows for the monitoring of pressure and allows for trapping and removal of air Additionally, the device includes an integral bubble trap, gross particulate filter

(105 μ) and pressure relief device designed to open in the event of excessive fluid pressure (600 mmHg) during use Solutions are delivered to the patient through the extension line and appropriate cannula Blood flow is driven by a roller pump connected through an extension line

The components of this system which have contact with the fluid path are sterile and nonpyrogenic

All blood contact materials of the Vision Blood Cardioplegia System with HA coating are biocompatible and coated with a proprietary coating

6 Indications for use

The Gish Vision Blood Cardioplegia System with HA coating is indicated for use in applications that require control of fluid temperature, such as blood or cardioplegia, typically in an extracorporeal circuit The device may be used for normothermic or hypothermic applications It is designed to operate at flow rates of one hundred (100) to six hundred (600) milliliters per minute for periods up to six (6 0) hours

7 Contra-indications

For HA coated blood cardioplegia systems, no contra-indications have been noted

8 Comparison

The Gish Vision Blood Cardioplegia System with HA Coating has the same device characteristics as the predicate devices

9 Test Data

The Gish Vision Blood Cardioplegia System with HA Coating has been subjected to extensive safety, performance, and validations prior to release Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications

10 Literature Review:

A review of literature pertaining to the safety and effectiveness has been conducted Appropriate safeguards have been incorporated in the design of Gish Vision Blood Cardioplegia System with HA Coating

11 Conclusions

Based upon the testing and comparison to the predict device the Gish Biomedical, Inc , Vision Blood Cardioplegia System with HA Coating has the same intended use, with similar technological characteristics Gish Biomedical, Inc , therefore posits that its device is equivalent in safety and effectiveness to predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 6 2009

Gish Biomedical, Inc
c/o Ms Janet Peets
Regulatory & Clinical Affairs Specialist
22942 Arroyo Vista
Rancho Santa Margarita, CA 92688

Re K081838
Vision Blood Cardioplegia and Extracorporeal Heat Exchanger with HA Coating
Regulation Number 21 CFR 870 4240
Regulation Name Cardiopulmonary Bypass Heat Exchanger
Regulatory Class Class II
Product Code DTR
Dated January 8, 2009
Received January 12, 2009

Dear Ms Peets

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Donna R. Vechner

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 081838

Device Name Gish Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger with HA Coating

Indications for use

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Prescription Device

Federal Law (US) restricts this device to sale by or on the order of a physician

Prescription Use Yes OR Over-The-Counter Use No

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Kochanek

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081838